111TH CONGRESS
1ST SESSION

# S. 1220

To require that certain complex diagnostic laboratory tests performed by an independent laboratory after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected shall be treated as services for which payment may be made directly to the laboratory under part B of title XVIII of the Social Security Act.

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IN THE SENATE OF THE UNITED STATES

JUNE 9, 2009

Mr. SPECTER (for himself and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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# A BILL

To require that certain complex diagnostic laboratory tests performed by an independent laboratory after a hospital outpatient encounter or inpatient stay during which the specimen involved was collected shall be treated as services for which payment may be made directly to the laboratory under part B of title XVIII of the Social Security Act.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Patient Access to Critical Lab Tests Act''.

**SEC. 2. FINDINGS; SENSE OF CONGRESS.**

(a) FINDINGS.—The Congress finds as follows:

(1) Timely access to laboratory testing is essential to ensure quality of care for patients.

(2) Genetic and molecular laboratory testing are the new cornerstones of high-quality, cost-effective preventive medicine.

(3) The completion of the Human Genome Project in 2003 paved the way for a more sophisticated understanding of disease causation, which has contributed to the advent of ''personalized medicine''.

(4) Personalized medicine is the application of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a patient's predisposition to a particular disease or condition.

(5) Personalized medicine offers the promise of smarter, more effective, and safer care as physicians and patients become equipped with better information to guide treatment decisions.

(6) Some of the most encouraging personalized medicine developments involve highly specialized laboratory tests that, using biomarkers and vast stores of historical data, provide individualized information

that enable physicians and patients to develop personalized treatment plans.

(7) Several outdated Medicare regulations for laboratory billing are obstructing access to highly specialized laboratory tests and delaying patients' diagnoses and treatments. These same rules are discouraging investments in development of new tests.

(8) Realizing the promise of personalized medicine will require improved regulation that appropriately encourages development of and access to these specialized tests.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) where practical, Medicare regulations and policies should be written to promote development of and access to the highly specialized laboratory tests referred to in subsection (a)(6); and

(2) the Medicare regulation described in section 414.510 of title 42, Code of Federal Regulations, is one such regulation that should be revised to permit laboratories furnishing certain specialized tests to bill for and be paid directly by Medicare for furnishing such tests.

**SEC. 3. TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS.**

(a) IN GENERAL.—Notwithstanding sections 1862(a)(14) and 1866(a)(1)(H)(i) of the Social Security Act (42 U.S.C. 1395y(a)(14) and 1395cc(a)(1)(H)(i)), in the case that a laboratory performs a covered complex diagnostic laboratory test, with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital, if the test is performed after such period the Secretary of Health and Human Services shall treat such test, for purposes of providing direct payment to the laboratory under section 1833(h) or 1848 of such Act (42 U.S.C. 1395l(h) or 1395w–4), as if such specimen had been collected directly by the laboratory.

(b) COVERED COMPLEX DIAGNOSTIC LABORATORY TEST DEFINED.—For purposes of this section, the term ''covered complex diagnostic laboratory test'' means an analysis—

(1) of DNA, RNA, chromosomes, proteins, or metabolites that detects, identifies, or quantitates genotypes, mutations, chromosomal changes, biochemical changes, cell response, protein expression, or gene expression or similar method or is a cancer chemotherapy sensitivity assay or similar method,

but does not include methods principally comprising routine chemistry or routine immunology;

(2) that is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3));

(3) that is developed and performed by a laboratory which is independent of the hospital in which the specimen involved was collected and not under any arrangements (as defined in section 1861(w)(1) of such Act (42 U.S.C. 1395x(w)(1)); and

(4) that is not furnished by the hospital where the specimen was collected to a patient of such hospital, directly or under arrangements (as defined in section 1861(w)(1) of such Act (42 U.S.C. 1395x(w)(1))) made by such hospital.

**SEC. 4. EFFECTIVE DATE.**

The provisions of section 3 shall apply to tests furnished on or after the date of the enactment of this Act.

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